

70127-10

6/23/2011

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
Washington, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

Carrie Daniels  
Authorized Representative of  
Novozymes Biologicals, Inc.  
Exponent  
1150 Connecticut Avenue, NW, Suite 1100  
Washington, DC 20036

RE: Product Name: Tick-Ex™ EC - Bioinsecticide  
EPA Reg. No: 70127-10  
Notification Dated: May 6, 2011 to add an Alternate Brand Name: Met52 EC  
as per PRN 98-10.

Dear Ms Daniels:

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under Pesticides Registration Notice (PRN) 98-10 dated above. A preliminary screen of this request has been conducted for its applicability under PRN 98-10 and it has been determined that the action(s) requested falls within the scope of PRN 98-10. Our records have been duly noted, and the label submitted with this application has been stamped as "**Notification Accepted**" and will be placed accordingly in our records.

Questions concerning this action should be directed to Mary Paden (703) 308-0411 or email at [paden.mary@epa.gov](mailto:paden.mary@epa.gov).

Sincerely,

*Sheryl K. Reilly*

Sheryl K. Reilly, Ph.D., Chief  
Microbial Pesticides Branch  
Biopesticides and Pollution Prevention  
Division (7511P)

JUN 23 2011

CONCURRENCES

SYMBOL	7511(P)						
SURNAME	Paden						
DATE	23 JUN 11						

**EPA**
 United States  
**Environmental Protection Agency**  
 Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number

**Application for Pesticide - Section I**

1. Company/Product Number 70127-10	2. EPA Product Manager Sheryl Reilly	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Novozymes Biologicals, Inc. / Tick-EX EC	PM# BPPD	
5. Name and Address of Applicant (Include ZIP Code)  Novozymes Biologicals, Inc. 5400 Corporate Circle, Salem, Virginia 24153  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. <b>Notification Accepted</b>  Product Name _____ Date: <u>06/23/2011</u> Reviewer: <u>Mary Roden</u>	

**Section II**

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated XX-XX-XX
<input type="checkbox"/> Resubmission in response to Agency letter dated	<input type="checkbox"/> "Me Too" Application
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of a notification to add an Alternate Brand Name to the registered product Tick-EX EC (EPA Reg. No. 70127-10).

**Section III**

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No  *Certification must be submitted	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per Container	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Package wgt. No. per Container	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) Plastic Bag
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container	5. Location of Label Directions <input type="checkbox"/> On Bag <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other Stickered onto bag <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

**Section IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Carrie Daniels	Title Authorized Representative	Telephone No. (Include Area Code) 202-772-4916
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)  <div style="border: 1px solid black; width: 100px; height: 100px; margin: 10px auto;"></div>
2. Signature BY: <u>Dean Thome</u>	3. Title Regulatory Affairs Manager, Novozymes Biologicals, Inc.	
4. Typed Name: Dean Thome	5. Date: May 5, 2011	

(Front Panel)

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# TICK-EX EC BIOINSECTICIDE

[ABN: MET52 EC]

<b>ACTIVE INGREDIENT</b> – <i>Metarhizium anisopliae</i> Strain 52*	% w/w
<b>OTHER INGREDIENTS**</b>	11.0%
<b>Total</b>	89.0%
	100.0%

\* Contains  $5.5 \times 10^9$  Colony Forming Units (CFU)/gram of Tick-EX EC based on  $5 \times 10^{10}$  viable conidia per gram of active ingredient.

\*\* Contains petroleum distillates

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

**Notification Accepted**

Date: 06/23/2011

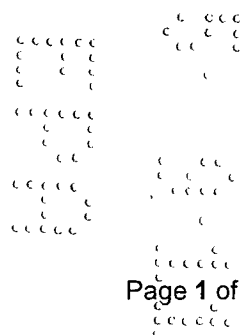
Reviewer: Mary Paden

## PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Causes moderate eye irritation. Harmful if inhaled, absorbed through skin, or swallowed. Avoid contact with skin, eyes, or clothing. Avoid breathing dust. Wash thoroughly with soap and water after handling, and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID	
<b>IF IN EYES:</b>	Hold eye open and rinse slowly and gently with water for 15 – 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
<b>IF INHALED:</b>	Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.
<b>IF ON SKIN OR CLOTHING:</b>	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes. Call a poison control center or doctor for treatment advice.
<b>IF SWALLOWED:</b>	Call a poison control center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor or going for treatment. For emergency information on this pesticide product (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Information Center at 1-800-858-7378, 6:30 AM to 4:30 PM Pacific Time (PT), seven days a week. During other times, call the poison control center at 1-800-222-1222.	
NOTE TO PHYSICIAN	
Contains petroleum distillate. Vomiting may cause aspiration pneumonia.	

Batch Code/Expiry Date: \_\_\_\_\_  
Net Contents: [1 gallon] [1 quart] [1 pint] [½ pint] [XX L]



EPA Establishment Number: [070127-VA-001]  
[085238-CAN-001]  
EPA Registration Number: 70127-10  
Made in [USA] [Canada]  
[www.bioag.novozymes.com]

[NOVOZYMES RETHINK TOMORROW] [LOGO]

## PERSONAL PROTECTIVE EQUIPMENT

Mixer/loaders, applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Waterproof gloves
- Shoes and socks
- Protective eyewear
- Dust-mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C) or a NIOSH approved respirator with any N-95, R-95, P-95 or HE filter.
- Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

## USER SAFETY RECOMMENDATIONS

- Users should remove clothing immediately if pesticide gets inside, then wash thoroughly and put on clean clothing.
- Remove personal protection equipment immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

## ENVIRONMENTAL HAZARDS

This product contains an ingredient that is toxic to fish. *This product is approved for residential (urban and suburban) outdoor terrestrial non-food and agricultural food uses.* Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate.

## PHYSICAL OR CHEMICAL HAZARDS

For spill, leak, fire, exposure, or accident, call CHEMTREC at 1-800-424-9300, day or night.

## DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the state or tribal agency responsible for pesticide regulation.

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## AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

For uses that are soil incorporated mechanically, there is a 0 hour Restricted Entry Interval (REI) - the Worker Protection Standard allows workers to enter the treated area if there will be no contact with anything that has been treated. For all other uses, do not enter or allow worker entry into treated areas during the REI of four hours.

PPE required for early entry to treated areas requiring a REI that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, plants, soil, or water are:

- Coveralls
- Waterproof gloves
- Shoes plus socks
- Protective eyewear
- Dust-mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C) or a NIOSH approved respirator with any N-95, R-95, P-95 or HE filter.

## NON-AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to uses that are NOT within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries or greenhouses.

Keep unprotected persons out of treated areas until sprays have dried.

## GENERAL

Tick-EX EC is composed of spores of the insect pathogenic fungus *Metarhizium anisopliae* strain F52. Once the product is sprayed onto the foliage or drenched into the soil, insects that come into contact with the fungus will become infected. The spores of *Metarhizium anisopliae* attach to the surface of the insect, germinate and begin to grow. It will penetrate the exoskeleton of the insect and grow inside the insect, causing the insect to die. Under moderate temperatures it usually takes 3 to 7 days, once the insect is exposed for death to occur. At very cold or hot temperatures death may occur more slowly. The fungal spores will be more persistent when incorporated in the soil, especially in potting media, than when applied to foliage.

Note: Tick-EX EC contains live spores that may be harmed by storage at high temperatures or held as a water suspension for more than 24 hours. See storage and disposal section for more information.

**(Reviewer Notes: This ends the label that will be placed on the front of the container.)**



(Reviewer Notes: This states the label that will be placed on the back of the container.)

**MODE OF ACTION AND APPLICATION TIMING:** Application frequency will depend on the environment to which Tick-EX EC is applied and the target insects' life cycle. Persistence of Tick-EX EC will generally be higher when incorporated into soil and higher in foliar applications in greenhouses than outdoor foliar.

Tick-EX EC may be used for foliar applications to control insects with a high reproductive potential. It is best to begin applying Tick-EX EC at early stages of population development. Repeat applications at 5-10 day intervals, matching application interval to insect and population. High insect populations of whiteflies may require 2-5 day intervals. Applications to leaf litter and turf may be done on a four to six week interval with an expected residual efficacy of a few months.

Applications of drenches to potting media may be done as appropriate to standard pest management practices and the product may remain efficacious for up to one year. When possible, application to soil should be done in advance of a target insect's life stage that will be passing through the first six inches of soil, with an expected residual efficacy of a few months. Although the penetration of Tick-EX EC into soil will vary greatly with soil type and level of irrigation it is best to target populations as close to the surface as possible or time application of Tick-EX EC with a soil incorporation event

Once the product is incorporated into the growing medium, insects that come into contact with the fungus become infected. The spores attach to the surface of the insect, germinate and grow. Under moderate temperatures it usually takes 3 to 7 days, once the insect is exposed for death to occur. At very cold or hot temperatures death may occur more slowly.

**PRE-HARVEST INTERVAL:** Pre-harvest interval for Tick-EX EC is zero (0) days. Tick-EX EC may be applied up to the day of harvest.

### SITES FOR USE

**TERRESTRIAL NON-FOOD:** Tick-EX EC can be used on the crops listed in Table 1 (greenhouse, nursery and outdoor sites including urban and suburban turf). Do not apply on poinsettias after bract formation. Tick-EX EC has shown plant safety but has not been tested on all varieties. Test Tick-EX EC on a small number of plants to check for potential damage before applying to a large number of plants.

**FOOD CROPS:** Tick-EX EC can be used on the crops listed in Table 1 (including greenhouse, nursery and outdoor agricultural sites). Tick-EX EC has shown plant safety but has not been tested on all varieties. Test Tick-EX EC on a small number of plants to check for potential damage before applying to a large number of plants.

### APPLICATION INSTRUCTIONS

**MIXING INSTRUCTIONS: Shake well before using.** Tick-EX EC may be applied using hand-held, ground and/or aerial spray equipment. Tick-EX EC contains emulsifiers and mixes readily in water. Fill spray tank with half of the desired amount of water and start agitation. Slowly add desired amount of Tick-EX EC to spray tank. Add remaining desired amount of water. Triple rinse empty Tick-EX EC container with water and add rinse water to spray tank. Continue agitation throughout spraying. Do not mix more Tick-EX EC than can be applied within six hours of mixing.

**PLANT SAFETY:** Tick-EX EC has been determined to be safe and efficacious for the uses described on this label but not been tested on all varieties of listed plant species. Test Tick-EX EC on a small number of plants to check for potential damage before applying to a large number of plants.

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**FOLIAR APPLICATION, HIGH VOLUME:** Apply at a rate of ½ pint to 1 quart per 100 gallons in high volume sprays (0.5 to 2.5 teaspoons per gallon). Mix well by external mixing, in-tank mixing, or pump circulation to form emulsion. Do not apply at pressures above 200 PSI. **Spray to wet all foliage, but avoid runoff.**

**FOLIAR APPLICATION, LOW VOLUME:** Apply ½ pt. to 2 quarts of Tick-EX EC to one (1) acre. Follow spray equipment manufacturer's instructions for final spray volume to obtain adequate coverage. Do not apply at pressures above 200 PSI. **Do not apply through a thermal pulse fogger.**

**DRENCH:** Add from 40 to 80 fluid ounces of Tick-EX EC to 100 gallons of drench solution. **For pots:** drench application should be thoroughly watered-in without causing water to come out of the bottom of the pots – depending on the soil type and moisture this will be around 8 ounces per gallon pot. **For soil applications:** drench application should be thoroughly watered-in without causing water to move laterally – this will vary by soil type and moisture holding capacity at time of application. Applications should be targeted to move Tick-EX EC into the top 2 inches of soil.

**FOLIAGE AND ROOT PLANT DIP:** To prepare dip solution, thoroughly mix ½ to 1 fluid ounce of Tick-EX EC per gallon of water. Prepare only as much dip solution as can be used in 6 hours. When treating plants by the dip method, thoroughly wet all plant surfaces to be treated. Allow treated plant foliage to dry prior to potting and watering. Tick-EX EC has been determined to be safe and efficacious for the uses described on this label but not been tested on all varieties of listed plant species. Test Tick-EX EC on a small number of plants to check for potential damage before applying to a large number of plants.

**APPLICATION TO TURF:** Apply 2 to 3 fluid ounces of Tick EX EC to 1000 square feet in residential and institutional lawns and landscape perimeters. Applications for blacklegged ticks should focus on the border of manicured lawns and paths creating a minimum of a 9 foot border. Applications for more mobile ticks such as lonestar tick should cover a wider area and include the entire lawn. Apply using a minimum of 4 gallons of water per 1000 square feet. Initial applications should begin in the spring before ticks become active and continue at 4 to 8 week intervals throughout their active season.

**TANK MIX COMPATIBILITY:** Tick-EX EC is physically and biologically compatible with a wide range of pesticides and spray adjuvants. Do not mix Tick-EX EC with fungicides. If adjuvants are required when applying Tick-EX EC in combination with other pesticides, contact your dealer or Novozymes Biologicals for specific recommendations.

Observe the most restrictive of the labeling limitations and precautions of all products used in mixtures.

**CONTROLLING PESTICIDE DRIFT:** Do not allow spray to drift from the application site and contact people, nontarget crops, aquatic and wetland areas, or animals.

For ground boom applications, apply with nozzle height no more than 4 feet above the ground or crop canopy and when wind speed is 10 mph or less at the application site as measured by an anemometer. Use a fine or medium spray according to ASAE 572 definition for standard nozzles or VMD for spinning atomizer nozzles.

For orchard/vineyard airblast applications, do not direct spray above trees/vines and turn off outward pointing nozzles at row ends and outer rows. Apply only when wind speed is 3 -10 mph at the application site as measured by an anemometer outside of the orchard/vineyard on the upwind side.

For aerial applications, the boom width must not exceed 75% of the wingspan or 90% of the rotary blade. Use upwind swath displacement and apply only when wind speed is 3 -- 10 mph as measured by an anemometer. Use medium or coarser spray according to ASAE 572 definition for standard nozzles or VMD for spinning atomizer nozzles. If application includes a no-spray zone, do not release spray at a height greater than 10 feet above the ground or the crop canopy.

The applicator also must use all other measures necessary to control drift.

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**TABLE 1: CROPS ON WHICH TICK-EX EC MAY BE USED:**

CROP	PEST	APPLICATION	RATE
Onions	thrips	drench	40-80 fl. oz./100 gal.
		foliar	0.5 pt.-2 qt./acre
Celery, lettuce, spinach	thrips, whiteflies, mites	drench	40-80 fl. oz./100 gal.
		foliar	0.5 pt.-2 qt./acre
Peppers, tomatoes	thrips, whiteflies, mites	drench	40-80 fl. oz./100 gal.
		foliar	0.5 pt.-2 qt./acre
Grape, strawberry, cranberry, raspberry, blackberry	thrips, whiteflies, mites, weevils	drench	40-80 fl. oz./100 gal.
		foliar	0.5 pt.-2 qt./acre
<b>Ornamental plants and grasses:</b> shrubs, vines, trees, lawn, bedding plants, etc.	thrips, weevils, mites	drench	40-80 fl. oz./100 gal.
		foliar	0.5 pt.-1 qt./100 gallons, spray to wet but avoid runoff.
<b>Turf:</b> institutional, residential lawns (urban and suburban)	ticks	drench	40-80 fl. oz./100 gal.
		foliar	1 to 3 fl. oz/ 1000 ft <sup>2</sup>

*Applicators other than homeowners*

**STORAGE AND DISPOSAL**

Do not contaminate water, food, or feed by storage or disposal.

**PESTICIDE STORAGE**

Store TICK-EX EC in its original container below 73°F (23°C) in a dry, locked place, out of the reach of children and out of direct sunlight. Do not use or store near heat or open flame. Use product within one year and by the expiry date noted on the label.

**PESTICIDE DISPOSAL**

To avoid wastes, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

**CONTAINER HANDLING**

Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling, if available, or puncture and dispose of in a sanitary landfill, or by incineration. Do not burn, unless allowed by state and local ordinances.



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## Homeowners

### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

#### PESTICIDE STORAGE

Store TICK-EX EC in its original container below 73°F (23°C) in a dry, locked place, out of the reach of children and out of direct sunlight. Do not use or store near heat or open flame. Use product within one year and by the expiry date noted on the label.

#### PESTICIDE DISPOSAL AND CONTAINER HANDLING

Nonrefillable container. Do not reuse or refill container.

##### If empty:

Place container in trash or offer for recycling, if available.

##### If partly filled:

Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

## WARRANTY

The Directions for Use of this product reflect the opinion of experts based on field use and tests. The directions are believed to be reliable and must be followed carefully.

Novozymes Biologicals warrants that at the time of the first sale of this product it conforms to the chemical description on the label and when used according to the label directions under normal growing conditions is reasonably fit for the purposes referred to above. To the extent consistent with applicable law, buyers/users of this product assume full risk for any use contrary to the specified directions. If this product does not perform as warranted above, customer's sole remedy for breach of warranty, to the extent consistent with applicable law, shall be replacement of the product or refund of the purchase price paid, at the option of Novozymes Biologicals.

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, EXCEPT AS PROVIDED ELSEWHERE IN WRITING CONTAINING AN EXPRESS REFERENCE TO THIS WARRANTY AND LIMITATION OF DAMAGES, SELLER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OR GUARANTEE, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR OF MERCHANTABILITY, AND NO AGENT OF SELLER IS AUTHORIZED TO DO SO.